UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,517	10/31/2003	Dale B. Schenk	015270-008920US	8113

20350 7590 04/07/2005

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,517	SCHENK ET AL.	
	Examiner	Art Unit	
	Christopher J. Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48 and 50-80* is/are pending in the application.

4a) Of the above claim(s) *1-40,42,56-70 and 72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-48,51-55 and 71-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48 and 50-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10.31.03 9.28.04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HJC

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V (claims 42 and 45-55) in the reply filed on 25 February 2005 is acknowledged. The traversal is on the ground(s) that the description of the agents used in Group IV and Group V are incorrect. The agent of Group IV is Aβ not α-synuclein and the agent of Group V is an antibody. Applicant is correct and the correction is noted herein. The Linking claims are included in the groups listed in the Restriction Requirement (2 February 2005). Accordingly, Claim 1 is included in Groups I, II, III, IV, and V. Claim 17 is included in Groups IV and V. Claims 41 and 44 are included in Groups IV and V. Claim 56 is included in Groups VI and VII. However, as Applicant has requested that Group V include claims 41, 42-48, 50-55, 71-80, the request is granted. The Examiner notes that claim 72 pertains to Aβ as the agent which is active immunization rather than passive immunization as originally elected. Therefore claims 41-48, 50-55, and 71-80 are under examination.

2. Claims **1-40** and **56-70** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 25 February 2005. The Examiner notes Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121. The remaining requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claim **43** is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not clear whether the "fragment" of claim 43 retains any structural or functional characteristics of the "antibody" in the same claim. Therefore it is not clear if this limitation further limits the "agent" of claim 41.

Obvious-Type Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims **41, 42, 45, 47, 48, 71, 72, 75, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-14 and 19-36 of U.S. Patent No. 6,787,138 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

5. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology may be a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '138 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '138 to treat the patient population of the instant application.

6. In addition, US '138 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

7. The method as taught by US '138 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '138 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.

8. Claims **41, 42, 45, 47, 48, 71, 72, 75, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-8, 11-12, 36-43, 46-47, and 51-54 of U.S. Patent No. 6,787,139 in view of Kotzbauer *et al.* (October 2001)

"Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

9. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology may be a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '139 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '139 to treat the patient population of the instant application.

10. Also US '139 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

11. The method as taught by US '139 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '139 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.'

12. Claims **41, 42, 45, 47, 48, 71, 72, 75, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,787,140 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

13. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology may be a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '140 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '140 to treat the patient population of the instant application.

14. Also US '140 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

15. The method as taught by US '140 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain.

Since US '140 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.

16. Claims **41, 42, 45, 47, 48, 71, 75, 77, 72,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-24 of U.S. Patent No. 6,787,143 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

17. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology may be a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '143 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '143 to treat the patient population of the instant application.

18. Also US '143 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

19. The method as taught by US '143 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '143 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.

20. Claims **41, 42, 45, 47, 48, 71, 72, 75, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8, 10, 11, 13-16, and 18-24 of U.S. Patent No. 6,787,144 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

21. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology may be a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '144 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '144 to treat the patient population of the instant application.

22. Also US '144 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no

known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

23. The method as taught by US '144 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '144 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.

24. Claims **41, 42, 45, 47, 48, 71, 72, 75, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, 7, 13, 14, 28-37, 39-43, 45-47, and 50 of U.S. Patent No. 6,866,849 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

25. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology may be a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '849 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '849 to treat the patient population of the instant application.

26. Also US '849 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77; and 78.

27. The method as taught by US '849 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '849 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.

28. Claims **41, 42, 45, 47, 48, 71, 72, 75, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 9, 10, 12, 13, 22, 27, 28, 30, 31, 33, 34, 43, 45, 46, 48, 49, 51, 52, 53, 62, 64, 65, 67, 68, 70, and 71 of U.S. Patent No. 6,866,849 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience 17(2): 225-232.

29. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology is a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '850 uses an Aβ fragment and an adjuvant to induce an immune response thereby prophylactically or therapeutically treating the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic

response against Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '850 to treat the patient population of the instant application.

30. Also US '850 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

31. The method as taught by US '850 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '850 teaches administration orally, subcutaneous, intramuscularly, topically, or intravenously, these routes are taken to meet the limitations of claims 45 and 75.

32. Claims **41, 45, 46, 47, 48, 71, 75, 76, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 6, 13, 17, 18, and 19 of U.S. Patent No. 6,743,427 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

33. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology is a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '427 uses an anti-Aβ antibody to prophylactically or therapeutically treat the disease which is an obvious variant of the instantly claimed method of using an agent that induces an immunogenic response against Aβ wherein said agent is an

antibody to Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '427 to treat the patient population of the instant application.

34. Also US '427 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

35. The method as taught by US '427 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '427 teaches administration intraperitoneally, orally, subcutaneous, intranasally, intramuscularly, topically, or intravenously on multiple occasions over a period of 6 months, these routes and regime are taken to meet the limitations of claims 45, 46, 75, and 76.

36. Claims **41, 45, 46, 47, 48, 71, 75, 76, 77,** and **78** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 11, 12, 26, 33, 34, and 35 of U.S. Patent No. 6,761,888 in view of Kotzbauer *et al.* (October 2001) "Lewy Body Pathology in Alzheimer's Disease." Journal of Molecular Neuroscience **17**(2): 225-232.

37. Kotzbauer *et al.* teaches that the coexistence of Lewy body pathology with Alzheimer's pathology is a specific manifestation of the cellular dysfunction central to Alzheimer's disease (pp. 228). Thus both a disease characterized by Lewy bodies or alpha-synuclein aggregates in the brain and a disease characterized by an amyloid deposit of Aβ encompass the same patient population. In addition, the method of US '888 uses an anti-Aβ antibody to prophylactically or therapeutically treat the disease which is an obvious variant of the instantly claimed method of

using an agent that induces an immunogenic response against Aβ wherein said agent is an antibody to Aβ. Therefore it would have been obvious to a person of ordinary skill in the art to use the method as taught by US '888 to treat the patient population of the instant application.

38. Also US '888 teaches practicing the method when the patient has Alzheimer's disease, is asymptomatic, has inherited risk factors indicating susceptibility to Alzheimer's disease, has no known risk factors for Alzheimer's disease thus meeting the limitations of instant claims 47, 48, 77, and 78.

39. The method as taught by US '888 can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since US '888 teaches administration intraperitoneally, orally, subcutaneous, intranasally, intramuscularly, topically, or intravenously on multiple occasions over a period of 6 months, these routes and regime are taken to meet the limitations of claims 45, 46, 75, and 76.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

40. Claims **41-43, 45-48, 50-55, 71-73,** and **75-80** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method of prophylactically or*

therapeutically treating a patient suffering from a disease characterized by Lewy bodies or alpha-synuclein aggregation in the brain comprising

administering to a patient an effective dosage of immunogenic Aβ,

does not reasonably provide enablement for *using other agents in practicing the above method.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims.

41. The claims are drawn very broadly to methods of prophylaxis or treatment, both *passive* and *active* immunization, a Lewy body related or alpha-synuclein aggregate related disease using an agent that induces an immunogenic response against Aβ.

42. The Specification teaches that neuritic plaques that are the classic pathological hallmark of AD. They contain beta-amyloid (Aβ) peptide and non-beta amyloid component (NAC) peptide. Aβ is derived from a larger precursor protein termed amyloid precursor protein (APP). NAC is derived from a larger precursor protein termed the non-beta amyloid component of APP, now more commonly referred to as alpha-synuclein. NAC comprises amino acid residues 60-87 or 61-95 of alpha-synuclein. Figures 5 and 6 teach active immunization of nontransgenic, SYN, APP, and SYN/APP with Aβ1-42 show lower detectable levels of amyloid and synuclein inclusions.

43. However, the claims as instantly elected are drawn to *passive* immunization, namely administration of an antibody or antibody fragment as well as *active* immunization, namely administration of an immunogenic peptide or agent. And the specification fails to provide guidance for the successful treatment of diseases characterized by Lewy bodies or alpha-

synuclein aggregation by administration of agents other than immunogenic fragments of Aβ1-42. Since resolution of the various complications in regards to immunization treatment regimes for Lewy body and alpha-synuclein-related diseases is highly unpredictable, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation. In order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed *in vivo* would require the *de novo* determination of formulations of the agents encompassed by the claims, as well as mutants thereof, with known signs and symptoms to correlate with a result ranging from the alleviation of symptoms. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed.

44. The specification as filed does not provide any guidance or examples that would enable a skilled artisan to use the disclosed methods of using any given agent defined so far in that it stimulates an immunogenic response against Aβ. Additionally, a person skilled in the art would recognize that predicting the efficacy of using any agent based solely on its performance of a single Aβ immunogenic fragment as highly problematic (see MPEP §2164.03). Thus, although the specification prophetically considers and discloses general methodologies of using the claimed methods, such a disclosure would not be considered enabling since the state of the treatment of Lewy body and alpha-synuclein-related diseases as highly unpredictable. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

(A) The breadth of the claims;
(B) The nature of the invention;

(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

45. The following references are cited herein to illustrate the state of the art of immunization treatment regimes.

46. On the breadth of the claims, Wakabayashi *et al.* (October 1999) "Widespread occurrence of α-synuclein/NCAP-immunoreactive neuronal inclusions in juvenile and adult-onset Hallervorden-Spatz disease with Lewy bodies." Neuropathology and Applied Neurobiology **25**(5): 363-368 teaches that α-synuclein is found in Hallervorden-Spatz disease (HSD), a species of the instantly claimed genus of diseases characterized by Lewy bodies (Figure 2). Thus the art supports the link between α-synuclein and HSD and it is plausible to use the instant working example of administering immunogenic Aβ (Figures 5-6 of the instant Specification). However, this art does not support or suggest the use any other therapeutic agents.

47. Furthermore Ma *et al.* (April 2003) "α-synuclein aggregation and neurodegenerative diseases." Journal of Alzheimer's Disease **5**(2): 139-148 teaches that α-synuclein is critical to the pathogenesis of Alzheimer's disease, Parkinson's disease, dementia with Lewy bodies, multiple system atrophy, amyotrophic lateral sclerosis, Hallervorden-Spatz disease, Down's syndrome with AD, progressive supranuclear palsy, and corticobasal degeneration (Table 2). Therefore it is plausible to use the method of administering immunogenic Aβ to treat diseases which share the common mechanism of a-synuclein aggregation (Figures 5-6 of the instant

Specification). But, this art does not support or suggest the use any other therapeutic agents nor does this art suggest that other commonalities are shared such that the instant example could be expanded to encompass it.

48. On the nature of the invention, Goldsby *et al.* (2002) Kuby Immunology 4th Ed. Chapter 18 "Vaccines" (pp. 449-465) teaches that passive immunization does not allow for the formation of immunological memory requiring continued dosages if the desired immunity is to be maintained. Also the issue of the antigenicity of the antibody administered must be taken into consideration because it can trigger and unwanted and possibly harmful immune response especially mouse antibodies administered to humans (pp. 451). And Goldsby *et al.* (2002) Kuby Immunology Chapter 18 "Vaccines" (pp. 449-465) teaches that active immunization is not predictable as peptides are not generally immunogenic. Therefore inadequate guidance is presented in the Specification to overcome these obstacles in practicing the invention to the full scope as claimed.

49. On the state of the art, Wakabayashi *et al.* (November 1998) "Accumulation of a-synuclein/NACP is a cytopathological feature common to Lewy body disease and multiple system atrophy." Acta Neuropathol **96**(5): 445-452 teaches that NACP or a-synuclein (the causative agent of Parkinson's disease) is intimately aggregated with Aβ (pp. 451). In addition, Wakabayashi *et al.* teaches how β-synuclein and γ-synuclein are not involved (Figures 1 & 2). Therefore the state of the art details a nexus between α-synuclein and Aβ with Parkinson's disease and not other undefined agents.

50. The specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges of applying results prophetic guidance to the immunization based treatment of Lewy body and alpha-synuclein aggregates.

51. Claims **44** and **74** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method of prophylactically or therapeutically treating a patient suffering from a disease characterized by Lewy bodies or alpha-synuclein aggregation in the brain comprising*

> *administering to a patient an effective regimen of an agent that induces an immunogenic response against alpha-synuclein and Aβ wherein said agents are alpha-synuclein NAC fragments and immunogenic Aβ fragments,*

does not reasonably provide enablement for *using other agents in practicing the above method.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims.

52. The claims are drawn very broadly to methods of prophylaxis or treatment, both *passive* and *active* immunization, a Lewy body related or alpha-synuclein aggregate related disease using an agent that induces an immunogenic response against Aβ and a second that induces an immunogenic response against α-synuclein.

53. The Specification teaches that neuritic plaques that are the classic pathological hallmark of AD. They contain beta-amyloid (Aβ) peptide and non-beta amyloid component (NAC) peptide. Aβ is derived from a larger precursor protein termed amyloid precursor protein (APP).

NAC is derived from a larger precursor protein termed the non-beta amyloid component of APP, now more commonly referred to as alpha-synuclein. NAC comprises amino acid residues 60-87 or 61-95 of alpha-synuclein. Figures 5 and 6 teach active immunization of nontransgenic, SYN, APP, and SYN/APP with Aβ1-42 show lower detectable levels of amyloid and synuclein inclusions.

54. However, the claims as instantly elected are drawn to *passive* immunization, namely administration of an antibody or antibody fragment as well as *active* immunization, namely administration of an immunogenic peptide or agent. And the specification fails to provide guidance for the successful treatment of diseases characterized by Lewy bodies or alpha-synuclein aggregation by administration of agents other than immunogenic fragments of Aβ1-42. Since resolution of the various complications in regards to *passive* immunization treatment regimes for Lewy body and alpha-synuclein-related diseases is highly unpredictable, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation. In order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed *in vivo* would require the *de novo* determination of formulations of the agents encompassed by the claims, as well as mutants thereof, with known signs and symptoms to correlate with a result ranging from the alleviation of symptoms. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed.

55. The specification as filed does not provide any guidance or examples that would enable a skilled artisan to use the disclosed methods of using any given agent defined so far in that it

stimulates an immunogenic response against Aβ and a second that induces an immunogenic response against α-synuclein. Additionally, a person skilled in the art would recognize that predicting the efficacy of using any agents based solely on its performance of a single Aβ immunogenic fragment as highly problematic (see MPEP §2164.03). Thus, although the specification prophetically considers and discloses general methodologies of using the claimed methods, such a disclosure would not be considered enabling since the state of the treatment of Lewy body and alpha-synuclein-related diseases as highly unpredictable. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) ~~The quantity of experimentation needed to make or use the invention~~ based on the content of the disclosure.

56. The following references are cited herein to illustrate the state of the art of immunization treatment regimes.

57. On the breadth of the claims, Wakabayashi *et al.* (October 1999) "Widespread occurrence of α-synuclein/NCAP-immunoreactive neuronal inclusions in juvenile and adult-onset Hallervorden-Spatz disease with Lewy bodies." Neuropathology and Applied Neurobiology **25**(5): 363-368 teaches that α-synuclein is found in Hallervorden-Spatz disease (HSD), a species of the instantly claimed genus of diseases characterized by Lewy bodies (Figure 2). Thus the art

supports the link between α-synuclein and HSD and it is plausible to use the instant working example of administering immunogenic Aβ and a second immunogenic α-synuclein such as an NAC fragment (Figures 5-6 of the instant Specification). However, this art does not support or suggest the use any other therapeutic agents.

58. Furthermore Ma *et al.* (April 2003) "α-synuclein aggregation and neurodegenerative diseases." Journal of Alzheimer's Disease **5**(2): 139-148 teaches that α-synuclein is critical to the pathogenesis of Alzheimer's disease, Parkinson's disease, dementia with Lewy bodies, multiple system atrophy, amyotrophic lateral sclerosis, Hallervorden-Spatz disease, Down's syndrome with AD, progressive supranuclear palsy, and corticobasal degeneration (Table 2). Therefore it is plausible to use the method of administering immunogenic Aβ and a second immunogenic α-synuclein such as an NAC fragment to treat diseases which share the common mechanism of α-synuclein aggregation (Figures 5-6 of the instant Specification). But, this art does not support or suggest the use any other therapeutic agents nor does this art suggest that other commonalities are shared such that the instant example could be expanded to encompass it.

59. On the nature of the invention, Goldsby *et al.* (2002) Kuby Immunology 4th Ed. Chapter 18 "Vaccines" (pp. 449-465) teaches that passive immunization does not allow for the formation of immunological memory requiring continued dosages if the desired immunity is to be maintained. Also the issue of the antigenicity of the antibody administered must be taken into consideration because it can trigger and unwanted and possibly harmful immune response especially mouse antibodies administered to humans (pp. 451). And Goldsby *et al.* (2002) Kuby Immunology Chapter 18 "Vaccines" (pp. 449-465) teaches that active immunization is not predictable as peptides are not generally immunogenic. Therefore inadequate guidance is

presented in the Specification to overcome these obstacles in practicing the invention to the full scope as claimed.

60. On the state of the art, Wakabayashi *et al.* (November 1998) "Accumulation of a-synuclein/NACP is a cytopathological feature common to Lewy body disease and multiple system atrophy." Acta Neuropathol **96**(5): 445-452 teaches that NACP or a-synuclein (the causative agent of Parkinson's disease) is intimately aggregated with Aβ (pp. 451). In addition, Wakabayashi *et al.* teaches how β-synuclein and γ-synuclein are not involved (Figures 1 & 2). Therefore the state of the art details a nexus between α-synuclein and Aβ with Parkinson's disease and not other undefined agents.

61. The specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges of applying results prophetic guidance to the treatment of Lewy body and alpha-synuclein aggregates.

---

62. Claims **41** and **71** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

63. The independent claims require "agent that induces an immunogenic response against Aβ" but do not require that the agent to possess any particular conserved structure or defined biological activity. Furthermore the art recognizes that "agent" can pertain to chemical entities, pharmaceutical compositions, proteins, peptides, non-peptide compounds, animal tissue extracts, nucleic acids, antisense molecules, peptidomimetic, transformed cells, antibodies, antibody

fragments, cyclic peptides, agonists, antagonists, inhibitors, enhancers, vegetable extracts, cell extracts, synthetic agents, biologically derived substances as well as proteinaceous substances, known, and unknown compounds.

64. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a recitation of desired activity. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

65. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement

"by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

66. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* wherein the court rejected: "a patent directed to method for inhibiting prostaglandin synthesis in a human host using an unspecified compound, in order to relieve pain without the side effect of stomach irritation, did not satisfy the written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing the activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since the invention consists of performing 'assays' to screen compounds in order to discover those with the desired effect, but the patent did not name even one compound that assays would identify as suitable for practice of the invention, or provide information such that one skilled in art could identify any suitable compounds, since the specification did not indicate that compounds are available in public depository, since claimed treatment method cannot be practiced without the compound, and since inventors thus cannot be said to have 'possessed' the claimed invention without knowing of the compound or a method certain to produce the compound." Thus said patent constituted an invitation to experiment to first identify, then characterize, and the use a therapeutic a class of compound defined only by their desired properties. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compound defined only by their desired properties.

67. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

68. Claims **43** and **73** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

69. The claims requires an antibody which binds to Aβ while the claims do not specific an epitope nor do the claims require that the antibody's target possess any particular conserved structure, or other distinguishing feature, such as a sequence. Thus, the claims are drawn to a genus of antibodies that is defined by binding anywhere, anyhow to Aβ.

70. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a recitation of a desired target specificity for the antibody in question. The specification does not identify any particular portion of the target (Aβ) that must be conserved, nor does it provide an epitope. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

71. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

72. In *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 20 January 2004) the CAFC held that "Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

73. Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR

antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application.

74. Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen."

75. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

76. Claims **44** and **74** rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

77. These independent claims require an "agent that induces an immunogenic response against alpha-synuclein" and "agent that induces an immunogenic response against Aβ" but do

not require that the agent to possess any particular conserved structure or defined biological activity. Furthermore the art recognizes that "agent" can pertain to chemical entities, pharmaceutical compositions, proteins, peptides, non-peptide compounds, animal tissue extracts, nucleic acids, antisense molecules, peptidomimetic, transformed cells, antibodies, antibody fragments, cyclic peptides, agonists, antagonists, inhibitors, enhancers, vegetable extracts, cell extracts, synthetic agents, biologically derived substances as well as proteinaceous substances, known, and unknown compounds.

78. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a recitation of desired activity. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

79. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient

detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

80. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* wherein the court rejected: "a patent directed to method for inhibiting prostaglandin synthesis in a human host using an unspecified compound, in order to relieve pain without the side effect of stomach irritation, did not satisfy the written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing the activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since the invention consists of performing 'assays' to screen compounds in order to discover those with the desired effect, but the patent did not name even one compound that assays would identify as suitable for practice of the invention, or provide information such that one skilled in art could identify any suitable compounds, since the specification did not indicate that compounds are available in public depository, since claimed treatment method cannot be practiced without the compound, and since inventors thus cannot be said to have 'possessed' the claimed invention without knowing of the compound or a method certain to produce the compound." Thus said patent constituted an invitation to

experiment to first identify, then characterize, and the use a therapeutic a class of compound defined only by their desired properties. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compound defined only by their desired properties.

81. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

82. Claims **43** and **73** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "a fragment thereof" fails to sufficiently specify the metes and bounds of what is meant by a fragment. It is not clear whether this encompasses non-binding fragments, binding fragments, or non-functional fragments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

83. Claims **41, 44, 45, 50, 71, 74, 75** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication US 2002/0187157 A1 (12 December 2002) Jensen *et al.*

84. Jensen *et al.* teaches a method of treating Parkinson's disease, a disease characterized by Lewy body or α-synuclein aggregation in the brain, comprising administering at least one amyloid protein including but not limited to Aβ and/or α-synuclein to stimulate an immune response and thereby treating the disease thus meeting the limitations of claims 4, 44, and 50 **([0044], [0054]-[0060], [0064]-[0068], [0073]-[0075], [0244, Example 1])**.

85. The amyloid vaccine as taught by Jensen *et al.* can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since Jensen *et al.* teaches administration parenterally by injection, subcutaneous, intracutaneously, intradermally, subdermally, or intramuscularly, these routes are taken to meet the limitations of claims 45 and 75 **([0137])**.

86. Jensen *et al.* teaches a method of preventing and/or ameliorating Parkinson's disease, a disease characterized by Lewy body or α-synuclein aggregation in the brain, comprising administering at least one amyloid protein including but not limited to Aβ and/or α-synuclein to stimulate an immune response and thereby effecting prophylaxis of the disease thus meeting the limitations of claims 71 and 75 **([0044], [0054]-[0060], [0064]-[0068], [0073]-[0075])**.

87. Claims **41, 44, 45, 50, 71, 74, 75** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication US 2003/00086938 A1 (8 May 2003) Jensen *et al.*

88. Jensen *et al.* teaches a method of treating Parkinson's disease, a disease characterized by Lewy body or α-synuclein aggregation in the brain, comprising administering at least one amyloid protein including but not limited to Aβ and/or α-synuclein to stimulate an immune

response and thereby treating the disease thus meeting the limitations of claims 4, 44, and 50 **([0044], [0054]-[0060], [0064]-[0068], [0073]-[0075], [0244, Example 1])**.

89. The amyloid vaccine as taught by Jensen *et al.* can be administered "peripherally" taken by the Examiner to mean that administration is remote from the sight of pathology, namely the brain. Since Jensen *et al.* teaches administration parenterally by injection, subcutaneous, intracutaneously, intradermally, subdermally, or intramuscularly, these routes are taken to meet the limitations of claims 45 and 75 **([0137])**.

90. Jensen *et al.* teaches a method of preventing and/or ameliorating Parkinson's disease, a disease characterized by Lewy body or α-synuclein aggregation in the brain, comprising administering at least one amyloid protein including but not limited to Aβ and/or α-synuclein to stimulate an immune response and thereby effecting prophylaxis of the disease thus meeting the limitations of claims 71 and 75 **([0044], [0054]-[0060], [0064]-[0068], [0073]-[0075])**.

Summary

91. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 31, 2005